2003 WL 22255819
--- F.R.D. ---
(Cite as: 2003 WL 22255819 (S.D.Fla.))

United States District Court,
S.D. Florida.

Francella PEREZ, Elizabeth Cepero, Jeanette Cepero, William Burney, Beth
Milstein Bouggarne, and Patricia Berni, on behalf of themselves and all others
similarly situated, Plaintiffs,
v.
METABOLIFE INTERNATIONAL, INC.,
Defendant.

No. 02-22850-CIV.

Sept. 26, 2003.

Consumers brought suit in state court against manufacturer of over-the-counter dietary supplement containing ephedra and caffeine, seeking establishment of a medical monitoring program. After removal, plaintiffs moved for class certification. The District Court, Huck, J., held that requirements for class certification were not satisfied.

Motion denied.

[1] Damages 43

115k43 Most Cited Cases

In order to prevail on a medical monitoring claim under Florida law, a plaintiff must demonstrate: (1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

[2] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Proposed classes in medical monitoring suit consisting of all Florida users of over-the-counter dietary supplement and all users of the supplement in other states where medical monitoring is recognized as a cause of action, were not sufficiently precise to permit class certification; both were overly broad and required individualized determinations of class membership. Fed.Rules Civ.Proc.Rule 23, 28 U.S.C.A.

[3] Federal Civil Procedure 176
170Ak176 Most Cited Cases

Court should deny class certification where the class definitions are overly broad, amorphous, and vague, or where the number of individualized determinations required to determine class membership becomes too administratively difficult. Fed.Rules Civ.Proc.Rule 23, 28 U.S.C.A.

[4] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Commonality requirement for class certification was not satisfied in suit under Florida law asserting medical monitoring cause of action against manufacturer of over-the-counter dietary supplement, as proving elements of claim would require many individualized determinations, such as how much of the supplement each class member ingested, what warning labels each class member was exposed to, and whether ingestion of the supplement significantly increased the risk of contracting a serious latent disease. Fed.Rules Civ.Proc.Rule 23(a)(2), 28 U.S.C.A.

[5] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Typicality requirement for class certification was not satisfied in suit under Florida law asserting medical monitoring cause of action against manufacturer of over-the-counter dietary supplement; six named plaintiffs showed great variance in dosages taken, duration of use, alleged symptoms from usage, health histories, age, and other risk factors, and across the class, even more individual differences which were critical to adjudication would emerge. Fed.Rules Civ.Proc.Rule 23(a)(3), 28 U.S.C.A.

[6] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Adequacy of representation requirement for class certification was not satisfied in suit under Florida law asserting medical monitoring cause of action against manufacturer of over-the-counter dietary supplement; any medical monitoring regime set up in instant suit might foreclose future class members from seeking medical monitoring for a condition not suffered by any of the named plaintiffs, and preclusive effect of providing medical monitoring to instant class might bar unnamed class members from bringing claims for injuries actually suffered. Fed.Rules Civ.Proc.Rule 23(a)(4), 28 U.S.C.A.

[7] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Predominance requirement for class certification was not satisfied in suit under Florida law asserting medical monitoring cause of action against manufacturer of over-the-counter dietary supplement; most, if not all, of elements of medical monitoring claim would require individualized proof, and thus any efficiency gained by deciding the common elements would be lost when separate trials were required for each class member in order to determine each member's entitlement to the requested relief. Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.

[8] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Superiority requirement for class certification was not satisfied in suit under Florida law asserting medical monitoring cause of action against manufacturer of over-the-counter dietary supplement; even if court were to find that the supplement could cause injuries, individualized inquiries would still be required to assure that the medical monitoring elements were met with respect to each class member, giving rise to severe manageability problems. Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.

[9] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Certification of injunctive class action was not appropriate in suit under Florida law asserting medical monitoring cause of action against manufacturer of over-the-counter dietary supplement; individual issues involved in determining whether a monitoring program was different from that normally recommended in the absence of exposure precluded a finding of cohesiveness. Fed.Rules Civ.Proc.Rule 23(b)(2), 28 U.S.C.A.

[10] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Rule authorizing class treatment in order to avoid inconsistent adjudications that would create "incompatible standards of conduct" for a defendant was not applicable to suit under Florida law asserting medical monitoring cause of action against manufacturer of over-the-counter dietary supplement, as there was nothing incompatible about different courts' permitting medical monitoring for some plaintiffs while denying it to others. Fed.Rules Civ.Proc.Rule 23(b)(1)(A), 28 U.S.C.A.

[11] Federal Civil Procedure 182.5
170Ak182.5 Most Cited Cases

Conditional class certification was not appropriate in suit under Florida law asserting medical monitoring cause of action against manufacturer of over-the-counter dietary supplement, where basic requirements for class certification were not met; moreover, allowing a class to be imprecisely defined in the hope of narrowing and redefining the class following the taking of medical evidence ran the risk of implicating various due process concerns and skewing the litigation approach of the parties. Fed.Rules Civ.Proc.Rule 23, 28 U.S.C.A.

John Hasan Ruiz, Luisa Maria Linares, Roberto Villasante, Miami, FL, for plaintiffs.

Ronald E. Cabaniss, Larry Dean Smith, Jason Paul Herman, Cabaniss, Smith, Toole & Wiggins, Maitland, FL, Andrew A. Braun, Ernest P. Gieger, Jr., Laborde & Laperouse, New Orleans, LA, for defendant.

ORDER DENYING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

HUCK, District Judge.

***1** THIS CAUSE is before the Court on Plaintiffs' Motion for Class Certification, filed June 23, 2003 [DE # 60]. The Court has considered Plaintiffs' Motion and Reply, Defendant's Memorandum in Opposition to the Motion for Class Certification, Defendant's Supplemental Affidavit of Edward Sherman, and Plaintiffs' Reply to Dr. Sherman's

Affidavit. In addition, the Court held oral argument on Plaintiffs' Motion on September 9, 2003. Upon consideration of these memoranda and the oral argument, the Court is persuaded that this case is not appropriate for resolution on a class basis and denies the Motion for Class Certification.

Factual Background

This case, originally filed in the Florida Eleventh Judicial Circuit Court, was removed to this Court on September 25, 2002. On January 31, 2003, Plaintiffs filed their First Amended Class Representation Complaint ("Complaint"), naming eight representative Plaintiffs, six of whom presently remain as named Plaintiffs: Francella Perez, Elizabeth Cepero, Jeanette Cepero, William Burney, Beth Milstein Bouggarne, and Patricia Berni. [FN1] See Complaint at ¶ ¶ 3-10. Plaintiffs allege that Defendant, which manufactures, distributes, and sells Metabolife 356 (an over the counter dietary supplement containing ephedra and caffeine that is marketed primarily for weight loss, increasing energy, and speeding up metabolism), promoted the product by misinforming and misleading consumers about serious risks and dangers that could result from ingesting the pills. *Id.* at ¶ 14-15. The product allegedly contains ingredients which can cause a variety of health risks, including death, intracranial hemorrhage, hypertension, heart palpitations, tachycardia, arrhythmias, dysrhythmias, myocardial infarctions, seizures, tremors, psychosis, nervousness, headaches, syncope, vertigo, and gastrointestinal distress. *Id.* at ¶ ¶ 16, 46. Plaintiffs allege that Metabolife included inadequate warnings on the bottle labels and failed to avoid unreasonable risk of serious injury by not properly formulating and testing the product before putting it on the market. *Id.* at ¶ 17-23.

In their one-count Complaint, Plaintiffs request injunctive and equitable relief, primarily in the form of a medical monitoring program funded by the Defendant, but also including injunctive relief requiring Defendant to finance and undertake various forms of research, data collection, and educational outreach on potential long-term medical effects of Metabolife 356 usage. *Id.* at pp. 20-21. Plaintiffs do not allege a specific present injury, but rather indicate medical monitoring is necessary in order to detect, at an early stage while prevention is still possible, future injuries resulting from their use of Metabolife 356. Although the Complaint includes few facts about each named Plaintiff's medical condition, history of usage of the product, or knowledge of the warnings, Defendant has deposed the named Plaintiffs and filed excerpts of the deposition transcripts, in addition to a summary of those excerpts. Defendant's Opposition to Class Certification, Ex. 4-9, 11.

***2** Francella Perez is a 24-year-old woman who took two Metabolife 356 pills twice a day for a little over a month in about October 2000, and experienced some rapid heartbeats and possible hand shaking while taking the pills. She has not reported any symptoms since discontinuing her use of the product. Defendant's Opposition, Ex. 4.

Jeanette Cepero, also 24 years old, used Metabolife for possibly as long as a year starting in February 1999, taking one pill three times a day. She has a family history that includes liver diseases, heart problems, and migraines, has a personal history of dizzy spells, panic attacks, and heart palpitations that have required consultation with a cardiologist, suffers from Crohn's disease, and had taken Fen-Phen, another diet drug, prior to Metabolife. She reports suffering panic attacks and nausea while taking Metabolife and heart palpitations since discontinuing use. Defendant's Opposition, Ex. 5.

William Burney is a 56-year-old man who took a total of only four Metabolife pills, two in the morning and two in the afternoon of August 13, 2002. He suffered an atrial fibrillation two days later requiring hospitalization for a period of more than three days. Mr. Burney has a family history of heart disease, colon cancer, and diabetes, has a medical history of hypertension, fatigue problems, and prostate cancer, had a prescription for an inhaler and diuretics, and had been told by his doctor that his medical and family history, combined with excessive weight, put him at risk for a number of serious medical problems. Defendant's Opposition, Ex. 6.

Beth Milstein Bouggarne is 35 years old and took two Metabolife 356 pills three times a day for about a year-and-a-half starting in April 2000, stopping after hearing about possible side effects. She states she suffered dizziness, headaches, heartbeat changes, and cold hands and feet at times while taking the product, and she was diagnosed with mitral valve prolapse at some point after discontinuing use. Defendant's Opposition, Ex. 7.

Patricia Berni is a 46-year-old woman who took two

Metabolife pills three times a day for over two years beginning in January 1999 without suffering any adverse effects until March 2001, when she states that she began to suffer gastritis, headaches, and problems with nervousness, which was also the same time that she and her husband had to close their business due to financial difficulties. Some of these symptoms have continued after she stopped taking the pills, and she states that some events trigger tachycardia, that she has suffered hair loss, and that she can no longer eat certain foods. Defendant's Opposition, Ex. 8.

Elizabeth Cepero, whose age is not specified but who is described as an "older woman" by Defendant, took one pill three times a day for three months in mid-1999, occasionally taking a fourth pill in the morning. She reports having felt jittery while taking the pills, having trouble falling asleep, and developing palpitations, anxiety, shortness of breath, and headaches on occasion. She continued to suffer milder palpitations after discontinuing use and currently suffers from depression. Her cardiologist indicated she should get a check up once a year for her tachycardia. Defendant's Opposition, Ex. 9.

***3** The Defendant's summary of the deposition transcripts also points out the varying degrees to which the named plaintiffs read, understood, and heeded the product warning labels. That summary also notes that none of these Plaintiffs' treating physicians have told any of them that they need medical monitoring due to their Metabolife 356 consumption or that Metabolife 356 was responsible for the symptoms or disorders they report. Defendant's Opposition, Ex. 11.

Statement of the Case

[1] Plaintiffs' Complaint seeks recovery for medical monitoring, a cause of action recognized in Florida even absent a physical injury. *See* *Petito v. A.H. Robins Co.*, 750 So.2d 103, 105 (Fla. 3d DCA 2000), *rev. denied*, 780 So.2d 912 (Fla.2001). The seven elements of a medical monitoring claim were recently set out by the Florida Third District Court of Appeals. In order to prevail in such a case, a plaintiff must demonstrate:

> (1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring process exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

Id. at 106-07. In that case, the court created and supervised a fund to be financed by the defendant to pay for the costs of a medical monitoring program which would be available to all class members. *Id.* at 107-08.

Plaintiffs here seek certification of a class with the six named Plaintiffs described above acting as representative class members and the law firm of John H. Ruiz, P.A., acting as class counsel. Plaintiffs offer two classes that they purport to represent: "(1) All persons in the State of Florida who ingested Metabolife 356 at the dosage levels recommended by the Defendant" and "(2) All persons residing in States within the United States that recognize a cause of action for medical monitoring who ingested Metabolife 356 at the dosage levels recommended by the Defendant." Plaintiffs' Motion for Class Certification at 5.

In order to state a claim that is appropriate for class treatment, the Federal Rules of Civil Procedure require that the suit meet four prerequisites, commonly referred to as numerosity, commonality, typicality, and adequacy of representation. *Piazza v. EBSCO Industries, Inc.*, 273 F.3d 1341, 1345 (11th Cir.2001). Specifically, the Rules provide that:

> One or more members of a class may sue on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims and defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

***4** Fed. R. Civ. Pro. 23(a).

To be certified as a class action, the case must then also meet one of three additional requirements. Fed. R. Civ. Pro. 23(b). Rule 23(b)(1) permits class treatment when "the prosecution of separate actions would create a risk of ... inconsistent or varying adjudications ... which would establish incompatible standards of conduct for the party opposing the class." Fed. R. Civ. Pro. 23(b)(1)(A). Alternatively, a class can be certified when injunctive relief or declaratory judgment is sought and the defendant has

"acted or refused to act on grounds generally applicable to the class." Fed. R. Civ. Pro. 23(b)(2). Finally, a class action is sustainable when "the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. Pro. 23(b)(3).

Plaintiffs claim that each of the four Rule 23(a) prerequisites for class certification have been met in this case. Plaintiffs further argue that any of the three Rule 23(b) requirements would provide grounds for class certification. Defendant, on the other hand, contends that the class is inadequately defined and that the class members are not clearly ascertainable. Further, Defendant contests the Plaintiffs' claim that this case involves sufficient common issues to warrant class treatment, argues that the named Plaintiffs do not have standing to bring this action, and denies that these Plaintiffs can satisfy the typicality prerequisite or any of the Rule 23(b) requirements.

Analysis

While the idea of class treatment of these claims has some initial appeal, a closer analysis makes clear that the inability to precisely define the class, the individual differences among named Plaintiffs and unnamed class members, the difficulty of applying varying and unsettled legal principles in multiple states, and the danger of foreclosing unnamed class members from suing for individual damages in the future all mitigate against adjudicating these claims in a class action. The appeal of hearing expert opinion on the alleged dangers of Metabolife 356 and deciding the medical merits of these claims in one, consolidated hearing is thus far outweighed by the difficulty of determining causation for the variety of disorders and injuries allegedly caused by Metabolife 356 ingestion and by the inefficiencies and potential inequities that would result from class treatment.

I. Class Definition

[2] The first step in determining whether a class should be certified is to decide whether the Plaintiffs have identified a class that exists and that can be precisely defined. *See* *Simer v. Rios*, 661 F.2d 655, 669 (7th Cir.1981) (holding that class treatment was inappropriate partly due to difficulties in defining the class and identifying its members). "An identifiable class is essential so that the Court can determine whether a particular claimant is a class member." *McGuire v. International Paper Co.*, No. 92-CV-593BRR, 1994 WL 261360, at *3 (S.D.Miss. Feb.18, 1994) (citing *DeBremaecker v. Short*, 433 F.2d 733, 734 (5th Cir.1970)). "A vague class definition portends significant manageability problems for the court." *Rink v. Cheminova, Inc.*, 203 F.R.D. 648, 660 (M.D.Fla.2001).

***5** The Plaintiffs here have provided definitions for two classes they seek to certify, which essentially include all Metabolife 356 users in Florida and all Metabolife users in other states where medical monitoring is recognized as a cause of action. At oral argument, possible modifications to these definitions were discussed, but, even when modified, neither class definition is sufficiently precise and determinable to identify the appropriate class members. Both are overly broad and would require individualized determinations as to who are class members. The failure of Plaintiffs to adequately define a class is thus, in itself, sufficient grounds for denial of Plaintiffs' Motion.

A. *Class Including States Other than Florida*

Including class members from states other than Florida appears particularly problematic due to differences and uncertainties in the law. Plaintiffs have filed a chart that discusses the status of medical monitoring claims in all fifty states. *See* Plaintiffs' Motion, Ex. E. A handful of states have rejected the claim completely, another minority have recognized it as an independent cause of action, others allow it only as an element of damages when the plaintiff has sustained a physical injury, and the vast majority have not yet addressed the question. Although it was not entirely clear from Plaintiffs' briefs which states were intended to be included in the category of states "that recognize a cause of action for medical monitoring," Plaintiffs' counsel represented at oral argument that the class definition should be restricted only to those four states that explicitly recognize medical monitoring as a separate cause of action even in the absence of a physical injury, specifically, Florida, Pennsylvania, Colorado, and Illinois.

Even with this more limited definition of the class, the Court would be required to create subclasses and apply state law to cases arising in each of those four states. This would be a particularly difficult task

where, as here, the law in at least two of these jurisdictions is not well settled. In both Colorado and Illinois, rather than citing authoritative state cases defining a cause of action for medical monitoring, the Plaintiffs' chart cites two federal cases where the judge predicted, in the absence of any state decisions, that those states' supreme courts would permit a separate cause of action for medical monitoring; in both cases, however, the court then denied the requested medical monitoring on other grounds. *See Carey v. Kerr-McGee Chemical Corp.*, 999 F.Supp. 1109, 1119 (N.D.Ill.1998) (predicting that "if faced with the precise issue now before the court, the Illinois Supreme Court would uphold a claim for medical monitoring without requiring plaintiffs to plead and prove either a present physical injury or a reasonable certainty of contracting a disease in the future," but then finding this prediction to be "a Pyrrhic victory" because the claims were barred by the relevant statute of limitations); [FN2] *Cook v. Rockwell International Corp.*, 755 F.Supp. 1468, 1477 (D.Colo.1991) (stating that "although Colorado has yet to do so, I conclude that the Colorado Supreme Court would probably recognize, in an appropriate case, a tort claim for medical monitoring" but then holding that "even assuming that the Colorado Supreme Court would recognize an individual tort claim for medical monitoring," he does not believe they would do so in this case). Because these predictions of state law were both untested by any appellate or state court and mooted by the particular finding in those cases, they do not provide an adequate basis for concluding that Colorado and Illinois allow an independent cause of action for medical monitoring. [FN3]

***6** Moreover, as Defendant noted at oral argument, if the Court were to extend the class even just to the one or two other states where state courts have explicitly defined the medical monitoring cause of action, none of these named plaintiffs would be sufficiently representative. "It is well-settled that prior to the certification of a class ... the district court must determine that at least one named class representative has Article III standing to raise each subclaim." *Prado-Steiman v. Bush*, 221 F.3d 1266, 1279-80 (11th Cir.2000). All of the named Plaintiffs are Florida residents, and the Complaint alleges that Florida medical monitoring law would apply to all of them. Therefore, none of these Plaintiffs would have standing to raise questions of state law for states other than Florida, and the Court would not have jurisdiction to evaluate the law of those other states. *See id.* at 1280 (noting that the standing threshold must be crossed before representative capacity can be addressed).

B. *Minimum Daily Dosage and Duration of Usage*

Moreover, Plaintiffs' class definition for both Florida and out-of-state class members is deficient in that it contains no limitation as to dosage or duration of ingestion, and individualized hearings or trials would thus be required just on class membership issues. Plaintiffs claim that the dosage when defined as "the levels recommended by the Defendant" is sufficiently precise to make identification of the class members possible. However, the "recommended levels" include a wide range of dosage levels. Although the Metabolife 356 labels changed throughout the years, they consistently include the same "recommendation" as to intake of the product, stating "one to two caplets two to three times per day, or every 4 hours .... DO NOT EXCEED EIGHT CAPLETS PER DAY." Each pill contains 12 milligrams of ephedra. Thus, the "recommended dose" could be as low as two caplets per day (24 milligrams of ephedra), or as high as six caplets (72 milligrams of ephedra), with a specific warning not to exceed eight caplets (96 milligrams of ephedra). Further, the class definition contains no minimum duration of usage. As currently stated, taking two pills on only one occasion would qualify an individual for class membership. In fact, the descriptions of the named Plaintiffs bear out this wide range of possible claimants. The named Plaintiffs alone ingested from two pills per day to six pills per day for a duration ranging from one day to over two years. For example, Mr. Burney took only four pills ever, while Ms. Elizabeth Cepero took three pills each day for more than two years.

To cure the likely over-inclusive range of the definition "at the levels recommended by the Defendant," the Defendant conceded that setting a minimum daily dosage level of 32 milligrams of ephedra, or three Metabolife pills, might be appropriate. [FN4] Adding this requirement would not obviate the need for individualized hearings to determine the amount of Metabolife 356 ingested by each putative class member on a daily basis; it would merely change the minimum from two pills to three pills. Moreover, either definition would still suffer from the fundamental problem that the Court may not inquire into the medical merits of a case at the class certification stage. *See Forman v. Data Transfer, Inc.*, 164 F.R.D. 400, 403 (E.D.Pa.1995) (holding

that the court could not determine class membership where the class definition required "addressing the central issue of liability to be decided in the case"); *see also* *Intratex Gas Co. v. Beeson*, 22 S.W.3d 398, 403 (Tex.2000) (noting a class "should not be defined by criteria that ... require an analysis of the merits of the case"). For the Court to determine, at this time, a minimum dosage level for class membership would require making a determination on the ultimate issue as to whether ingestion of fewer than two or three pills a day can result in increased risk of injury. Although Plaintiffs claim conditional certification can cure this definitional problem by allowing modification of the class definition after medical evidence has been heard, the Court rejects conditional certification for the reasons set out in Part III.

C. *Proving Class Membership*

***7** [3] Even if the class definition could be refined by adding a minimum daily dosage and minimum duration of ingestion, there would still be serious problems with determining who is entitled to class membership. A court should deny class certification where the class definitions are overly broad, amorphous, and vague, or where the number of individualized determinations required to determine class membership becomes too administratively difficult. *See, e.g.*, *White v. Williams*, 208 F.R.D. 123, 129-30 (D.N.J.2002); *McGuire v. International Paper Co.*, No. 92-CV-593, 1994 WL 261360, at *4 (S.D.Miss. Feb.18, 1994). Here, unlike in many mass torts or toxic exposure cases, where passenger lists, employment records, or public records can be used to confirm class membership, it is unlikely that many of these putative class members will be able to produce objectively verifiable proof that they ingested the relevant amounts of Metabolife 356 for the relevant period of time.

As noted at oral argument, this problem was also presented to the judge who certified a class of individuals who had taken the appetite suppressants commonly referred to as Fen-Phen. *See* *In re Diet Drugs*, No. CIV 98-20626, 1999 WL 673066 (E.D.Pa. Aug.26, 1999). In that case, however, the judge decided that this difficulty should not bar class adjudication because there were reliable means short of a full blown hearing or trial of determining whether the class members had actually taken the drug. *Id.* at *13. Specifically, the judge noted that fact sheets, prescription records, and records of medical treatment could be used to verify consumption. *Id.* Here, because Metabolife is an over-the-counter product, no prescription records will exist, and since the majority of these medical monitoring claims will be for injuries that have not yet occurred, few class members are likely to be able to produce medical records from doctor visits which document any Metabolife 356 use. Thus, the only evidence likely to be offered in many instances will be the putative class members uncorroborated claim that he or she used the product. Although Plaintiffs suggested that class membership could be determined through affidavits and fact sheets, allowing such uncorroborated and self-serving evidence without giving Defendant an opportunity to challenge the class member's evidentiary submissions would likely implicate Defendant's due process rights. This is especially true given that Metabolife is only one of several products containing ephedra, at least two others of which have very similar names. [FN5] Thus, any written submissions that do not give the Defendant an opportunity to challenge the memory or credibility of the individual making that averment would provide inadequate procedural protection to the Defendant. Therefore, individualized mini-trials would be required even on the limited issue of class membership. In a case where the district court similarly determined that "an inestimable number of individual hearings" would be required just to determine class membership, the court denied class certification, finding that "the judicial and litigation costs of making these threshold determinations would eliminate any possibility that a class action would yield any of its intended efficiencies." *McGuire*, 1994 WL 261360, at * 5.

II. **Rule 23 Requirements**

***8** As noted, the four requirements of numerosity, commonality, typicality, and adequacy of representation must be met before any civil suit can be certified as a class action. The problems with the numerosity prerequisite has largely been discussed above in the context of the class definition problems. See *Mauldin v. Wal-Mart Stores, Inc.*, No. 01-CV-2755, 2002 WL 2022334, at *5 n. 2 (N.D.Ga. Aug.23, 2002) (noting that the adequacy of the class definition is typically considered part of the numerosity inquiry but that some courts have found this to be a separate question to be determined prior to analyzing the Rule 23(a) prerequisites). The Plaintiffs have similarly failed to demonstrate satisfaction of the other three prerequisites and the Rule 23(b) requirements.

A. *Commonality, Typicality, and Adequacy of the Parties*

As the Eleventh Circuit has recognized, "the commonality and typicality requirements of Rule 23(a) overlap. Both requirements focus on whether a sufficient nexus exists between the legal claims of the named class representatives and those of individual class members to warrant class certification." *Prado-Steiman v. Bush*, 221 F.3d 1266, 1278-79 (11th Cir.2000). The commonality element refers to the class characteristics as a whole, whereas the typicality requirement concerns the individual characteristics of the class members in relation to the class. *Id.* The "adequacy of the parties" requirement has two prongs, the second of which asks whether "plaintiffs have interests antagonistic to the rest of the class." *See Griffin v. Carlin*, 755 F.2d 1516, 1532-33 (11th Cir.1985). [FN6] It has been noted that mass tort claims typically do not lend themselves to class treatment. *See, e.g., Georgine v. Amchem Products, Inc.*, 83 F.3d 610, 628 (3d Cir.1996), *aff'd sub nom. Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997) ("[I]ndividualized issues can become overwhelming in actions involving long-term mass torts (*i.e.* those which do not arise out of a single accident)."); *Castano v. American Tobacco Co.*, 84 F.3d 734, 746 (5th Cir.1996) ("It is no surprise, then, that historically, certification of mass tort litigation cases has been disfavored.").

[4] Plaintiffs claim that this case involves at least five common questions of law and fact: (1) whether Metabolife 356 is dangerous, (2) whether Metabolife International, Inc., was negligent, (3) whether Metabolife 356 causes increased risk of contracting serious latent diseases, (4) whether monitoring procedures exist for any such diseases, and (5) whether a monitoring regime is reasonably necessary. Plaintiffs' Motion at 10. The Defendant, on the other hand, contends that these Plaintiffs are not typical of the class and that the claims of the class members require primarily individualized inquiry which overwhelm any commonality. [FN7] It should also be noted that, while Plaintiffs argue that the Court may not inquire into the merits of the case at the class certification stage, it is, nonetheless, necessary to look beyond the pleadings in order to determine whether the Rule 23 requirements for class certification have been met. [FN8]

***9** Although the commonality requirement is not a high threshold and generally only requires one common question of law or fact, the requirement is greater when the plaintiffs seek, as here, to resolve all issues, including the non-common issues, in one proceeding. *See Barnes v. American Tobacco Co.*, 161 F.3d 127, 140 (3d Cir.1998). As such, Plaintiffs have not met this burden of demonstrating sufficient commonality. In order to recover in this action, Plaintiffs must prove the seven elements of the medical monitoring claim recognized as a cause of action in Florida. *See Petito v. A.H. Robins Co.*, 750 So.2d 103 (Fla. 3d DCA 1999), *rev. denied*, 780 So.2d 912 (Fla.2001). Despite Plaintiffs' assurances to the contrary, the elements of that cause of action will require many individualized determinations. A Florida Circuit Court conducting a similar analysis in a toxic exposure case found that all seven *Petito* elements required case-specific determinations and could not, therefore, be decided on a class-wide basis. *See Hoyte v. Stauffer Chemical Co.*, No. 98-3024-Cl-7, 2002 WL 31892830, at *48-*52 (Fla.Cir.Ct. Nov.6, 2002). That court noted that "medical monitoring is not just a form of relief, it is a separate cause of action with seven specific elements the plaintiffs must establish ..., including three that expressly require proof of a monitoring program that meets particular standards." *Id.* at *51. To the extent that any of the seven elements can be found to involve common issues, the individual issues predominate, and class certification is not appropriate under the Rule 23(b) requirements, discussed below. In that regard, the advantages of class treatment on any common issues are outweighed by the difficulty and inefficiency of managing a class action requiring mini-trials for nearly every class member.

The first element, above-normal exposure to a substance, will require the individualized determinations as to whether each class member had actually ingested this product, with all the attendant difficulties noted above of making such factual determinations in the absence of written documentation. The second element requires a determination as to whether Metabolife 356 is dangerous or hazardous. Unless the product is found to be inherently hazardous, such a finding may well depend on individual considerations. For example, Metabolife 356 may be dangerous to an individual who is simultaneously taking certain prescription drugs or to one who had already suffered heart palpitations, such as Plaintiff Jeanette Cepero, but still be safe for individuals on no medication and with

no history of medical disorders.

The third element, proof of negligence by the Defendant, may depend largely on individualized issues related to what warning labels the particular class member received and whether the Defendant can defend by proving that the individual was comparatively negligent by ignoring warnings regarding contraindications or health risks for people suffering from certain conditions. As the factual summaries demonstrate, these issues are not common to the class. Different warning labels were affixed to the bottles throughout the years, and the extent to which just these six individuals read, understood, and abided by the warnings varied greatly. [FN9]

***10** The fourth element requires essentially proof of proximate causation: each Plaintiff must demonstrate that the use of Metabolife 356 significantly increased the risk of contracting a serious latent disease. *See Rink v. Cheminova, Inc.*, 203 F.R.D. 648, 661 (M.D.Fla.2001) ("[W]hether a putative class member has a significantly increased risk of contracting a serious latent disease ... is not at all a common issue ... and would necessarily depend upon the varied circumstances of the class members' exposure and other factors which may increase risk of disease."). This element is thus particularly unsuitable for class treatment. Even just these six Plaintiffs, whose ages and medical conditions run the gamut, will present very different fact patterns that may be inappropriate for disposition in a single case. One is a 24 year-old woman with few health problems, while another is a 24-year-old woman with several health problems, including Crohn's disease. How these two women's health affects their susceptibility to any increased risk of injury due to Metabolife ingestion will necessarily require individualized expert medical testimony. Other Plaintiffs suffer from different illnesses or risk factors that could affect their susceptibility to an increased risk. Further, Plaintiffs have listed sixteen injuries that they claim Metabolife 356 can cause. Given the vast differences in individual class members, determining increased risk for one disorder would be difficult enough, but evaluating whether each member is at an increased risk of contracting up to sixteen latent diseases would be unmanageable in the framework of a class action.

The last three *Petito* elements involve the specific medical monitoring regimen that a plaintiff is entitled to undergo. Plaintiffs suggest that a uniform program can be established for all class members, but again ignore the significant individual differences that make such uniformity impossible. *See Hoyte*, 2002 WL 31892830, at *51 ("[T]he focus of medical monitoring should be on the individual, and individual risk factors and preferences must be considered in recommending any medical monitoring regime."). Particularly, the sixth element requires a finding that the prescribed monitoring protocol is one that would not normally be recommended in the absence of an exposure. This element demands individualized rulings, because many of the individuals would normally be recommended to undergo exactly the same diagnostic screenings and tests based on risk factors other than Metabolife 356 use. For example, even had she never taken Metabolife 356, Plaintiff Jeannette Cepero's physician likely would recommend that she undergo certain diagnostic tests for her heart because of her prior Fen-Phen use and history of heart palpitations, and Plaintiff William Burney's doctor, who told him he was at risk for a number of serious medical conditions due to his family and personal medical history, would probably recommend various medical tests regardless of whether he had taken four Metabolife 356 pills on September 13, 2002. Giving all class members a right of access to the same uniform monitoring program would allow these high-risk individuals to obtain free medical tests that the medical community would normally recommend for them in the absence of exposure. Thus, disparate treatment based on individual differences is not only appropriate, but is actually required by the definition of this cause of action. Further, the seventh element--whether monitoring is medically necessary--is likely to be an individualized matter. Defendant claims, for example, that the only individuals who might benefit from medical monitoring are chronic users who are currently still using Metabolife 356. If true, this would also require separate determinations regarding history of usage for each class member.

***11** [5][6] For many of these same reasons, the Court finds that Plaintiffs are not typical of the class and that they cannot adequately represent the class. These six individuals show great variance in dosages taken, duration of use, alleged symptoms from usage, health histories, age, and other risk factors. Across the class, even more individual differences which are critical to adjudication under *Petito* will emerge. Given the breadth of the relief sought, typicality would be nearly impossible to satisfy. This problem also implicates the adequacy of representation, because any medical monitoring regime set up here may

foreclose future class members from seeking medical monitoring for a condition not suffered by any of these named plaintiffs. Further, the preclusive effect of providing medical monitoring to this class may bar unnamed class members from bringing claims for injuries actually suffered. *See* *Hoyte*, 2002 WL 31892830, at *42-*43. [FN10] This would create a conflict between the named Plaintiffs and any unnamed members who had sustained an actual injury, thus making these representatives inadequate.

B. *Rule 23(b) Requirements*

Because the Court has found this case does not satisfy the basic class action requirements of providing an adequate definition or presenting common claims and typical claimants, the Rule 23(b) inquiry is not necessary. Nonetheless, Plaintiffs would be unable to demonstrate the appropriateness of a class action under any of the Rules 23(b) categories.

1. *Predominance and Superiority*

[7] Under Rule 23(b)(3), a class action can be certified if the Court finds that common questions of law or fact predominate and if class treatment is superior to other methods of adjudicating class members' claims. "The predominance inquiry ... is far more demanding than Rule 23(a)'s commonality requirement." *Jackson v. Motel 6 Multipurpose, Inc.*, 130 F.3d 999, 1005 (11th Cir.1997). As noted above, the Court is not convinced that even the low threshold of commonality has been met. Most, if not all, of the elements of the medical monitoring claim will require individualized proof, and, thus, any efficiency gained by deciding the common elements will be lost when separate trials are required for each class member in order to determine each member's entitlement to the requested relief. To the extent that there are elements of the medical monitoring claim that could possibly be determined on a class-wide basis, these sub-issues cannot be separated out from those that require individualized treatment unless the common issues in the action as a whole predominate. *See* *Kemp v. Metabolife International Inc.*, No. CIV 00-3513, 2002 WL 113894, at *4 (E.D.La. Jan.25, 2002). The "predominance requirement cannot be satisfied by seeking to repeatedly split the claims pursuant to Rule 23(c)(4)," when, as here, "liability as to Plaintiffs is, overall, a highly individuated issue." *Id.* A judge in the Middle District of Florida denied class certification in a medical monitoring case partly due to concerns that resolution of any common issues on a class basis would not even necessarily achieve any efficiency because "the juries in the hundreds or tens of thousands of 'min-trials' on causation and damages would be required to reconsider the findings of the original jury in the liability case in order to compare and apportion fault." *Rink v. Cheminova, Inc.*, 203 F.R.D. 648, 652 (M.D.Fla.2001).

***12** [8] As to superiority, the Court cannot see how treatment as a class action would be superior in any instance. Severe manageability problems are a prime consideration that can defeat a claim of superiority. *See* *Castano v. American Tobacco Co.*, 84 F.3d 734, 748 (5th Cir.1996). In this case, even if the Court were to find that Metabolife 356 can cause injuries, individualized inquiries would still be required to assure that the medical monitoring elements were met with respect to each class member. Managing these individual trials would make the process difficult and inefficient. Several other courts have denied class certification under similar circumstances, finding that predominance and superiority were not met where "the economies of scale achieved by class treatment are more than offset by the individualization of numerous issues relevant to a particular plaintiff." *In re American Medical Systems, Inc.*, 75 F.3d 1069, 1086 (6th Cir.1996) (listing other cases where class certification was denied). Further, the lack of a significant number of prior individual trials may mitigate against a class action. "Fairness may demand that mass torts with few prior verdicts or judgments be litigated first in smaller units--even single-plaintiff, single-defendant trials--until general causation [and] typical injuries become established." *Castano*, 84 F.3d at 748 (quoting Manual for Complex Litigation § 33.26).

2. *Injunctive Class Actions*

[9] Plaintiffs claim, alternatively, that this case can be certified under one of the first two class action categories due to its primarily injunctive nature. Rule 23(b)(2) allows class actions for injunctive or declaratory relief where the class opponent "has acted or refused to act on grounds generally applicable to the class." Fed. R. Civ. Pro. 23(b)(2). Although this rule does not have the same superiority and predominance requirement of Rule 23(b)(3), the class proponent must still demonstrate that the claims are cohesive. *See* *Barnes v. American Tobacco Co.*, 161 F.3d 127, 143 (3d Cir.1998). In fact, the class claims under this subpart "may require more cohesiveness

than a [Rule 23](b)(3) claim .... because in a [Rule 23] (b)(2) action, unnamed members are bound by the action without the opportunity to opt out." *Id.* Thus, a court should be hesitant to grant certification on this ground when individual issues and disparate factual circumstances are likely to overwhelm any common issues. *See id.* In fact, the *Barnes* case involved a medical monitoring claim in Pennsylvania that required proof of the same seven elements recognized in Florida. In that case, the court noted the many individual issues involved in determining whether a monitoring program is "different from that normally recommended in the absence of exposure" precluded a finding of cohesiveness under Rule 23(b)(2). *Id.* at 146. Because the Court has noted this same problem in this case, cohesiveness has not been shown, and the Court cannot certify the action under Rule 23(b)(2).

***13** Plaintiffs, however, cite the class certification order involving Fen- Phen diet drugs, stating that it supports that Rule 23(b)(2) permits certification even when many individual issues are involved. *See* Plaintiffs Reply to Professor Sherman's Affidavit at 5; *In re Diet Drugs*, No. Civ. A. 98-20626, 1999 WL 673066, at *14 (E.D.Pa. Aug.26, 1999). However, as the Court noted during oral argument, that case can be distinguished because it relied on established scientific evidence that two specific valvular disorders could be caused by use of Fen-Phen, because class membership could be more easily proven through prescription and other medical records, and because other individual issues were less prominent than they are in this case. *See Diet Drugs*, 1999 WL 673066, at *11-*12. In addition, that court only conditionally certified the class, noting that it could exclude parts of the class or decertify the class entirely if individual issues proved to destroy cohesion or deny constitutional rights to the parties. *Id.* at *13. That court also found that "there is sufficient medical study and research at this time to warrant conditional certification," *id.* at *18, a claim that cannot be made in this case. Moreover, a district court has substantial discretion in deciding whether to certify a class action. *See Heaven v. Trust Co. Bank*, 118 F.3d 735, 737 (11th Cir.1997); *Forehand v. Florida State Hospital at Chattahoochee*, 89 F.3d 1562, 1569 (11th Cir.1996). Although it certified the class action, the court in the *Diet Drugs* case noted significant manageability problems, stating that "[t]here exist individual issues which will be a challenge to the court and the parties in resolving the class claims, including individual factual issues and variance of applicable state law." *Diet Drugs*, 1999 WL 673066, at *18. This Court believes that these manageability problems predicted and since encountered by that Pennsylvania District Court would only be magnified in this case, where there are more individualized issues and where fewer of them are susceptible to proof through objective methods which would allow the Court to avoid hearings or "mini-trials" for each class member.

[10] Finally, Plaintiffs argue that Rule 23(b)(1)(A) permits class certification in this case. That rule allows for class treatment in order to avoid inconsistent adjudications that would create "incompatible standards of conduct" for the defendant. Fed. R. Civ. Pro. 23(b)(1)(A). "The phrase 'incompatible standards of conduct' refers to the situation where 'different results in separate actions would impair the opposing party's ability to pursue a uniform course of conduct.' " *In re Paxil Litigation*, 212 F.R.D. 539, 552 (C.D.Cal.2003) (quoting 7B Wright, Miller & Kane, *Federal Practice & Procedure: Civil 2d* § 1790 (2d ed.1986)). However, "inconsistent" adjudications in cases involving these putative class plaintiffs is to be expected, since individual differences in risk factors, medical histories, and history of usage of Metabolife 356 may make medical monitoring inappropriate for some class members even if it is found to be warranted for others. As such, there is nothing incompatible about different courts' permitting medical monitoring for some plaintiffs while denying it to others.

***14** Plaintiffs, however, state that the need for a uniform medical monitoring regimen creates a risk that multiple adjudications would lead to incompatible results. Plaintiffs Reply at 6-7. However, the Plaintiffs have not shown that a uniform medical monitoring plan is either appropriate or workable. As noted above, the various individual factors will likely affect the level of medical monitoring, if any, that is appropriate for each specific individual. In other words, a uniform program would simply convert this class action into free health care, where class members would get diagnostic testing paid for by Metabolife despite the absence of proof that the particular individual was at an increased risk of contracting a disease or suffering a specific injury. In fact, a uniform program would allow a person with a high risk of certain heart disorders to obtain a medical examination for the price of a bottle of Metabolife 356. Therefore, medical monitoring and preventative care would have to be custom-tailored to each individual in order to

account for these vast differences in usage and risk of injury. [FN11]

Plaintiffs also contend that the Court's reasoning for certifying a class in *Gasperoni v. Metabolife International, Inc.* under Rule 23(b)(1)(A) can be extended to this case. No. 00-71255, 2000 WL 33365948 (E.D.Mich. Sept.27, 2000). In *Gasperoni*, however, the Court was asked to rule on a class basis solely on the question of "whether the label on Metabolife 356 is materially misleading," and the requested injunctive remedy would have required modification of those labels and posting of notice at locations where the product was being sold. *Id.* at *1-*2. Thus, in that case, an order from another court requiring a different modification of the label or posting of a different warning could have created incompatible standards, since the company might then be unable to uniformly label their product while still abiding by all relevant court orders. Here, however, different individualized medical monitoring plans ordered by different courts would not lead to any such incompatibilities.

III. **Conditional Certification**

[11] At oral argument, Plaintiffs' counsel suggested that the problems with the class definition could easily be resolved by conditionally certifying the class as defined and then refining the definition based on medical evidence and by creating subclasses where necessary based on differences in the legal requirements of separate states or the medical implications of different conditions. The Court rejects this suggestion as inconsistent with the requirement that the four Rule 23(a) prerequisites must be met and one of the three Rule 23(b) requirements must be found before any class can be certified. *See Castano v. American Tobacco Co.*, 84 F.3d 734, 741 (5th Cir.1996) (noting that just because the rule allows conditional certification, "it does not follow that the rule's requirements are lessened when the class is conditional"); *In re Hotel Telephone Charges*, 500 F.2d 86, 90 (9th Cir.1974) ("Conditional certification is not a means whereby the District Court can avoid deciding whether, at the time, the requirements of the Rule have been substantially met"). [FN12]

***15** In addition, allowing a class to be imprecisely defined in the hope of narrowing and redefining the class following the taking of medical evidence runs the risk of implicating various due process concerns and skewing the litigation approach of the parties. For example, it establishes problems with notification and opt out procedures, since members may be cut from or added to the class after substantially all of the proceedings have been conducted depending on what the medical evidence establishes. *See In re Paxil Litigation*, 212 F.R.D. at 545. The uncertainty of the class definition could also severely affect settlement discussions, since the parties would not know how many members the class would include. *Id.* at 545-46. [FN13] Inappropriately treating this as a class action could also "create [ ] insurmountable pressure on defendant[ ] to settle" where "[t]he risk of facing an all-or-nothing verdict presents too high a risk, even when the probability of an adverse judgment is low." *Castano*, 84 F.3d at 746; Manual for Complex Litigation 3d § 30.11, at 215 (1995) ("Undesirable consequences may follow when an expansive class, formed on insufficient information, is later decertified or redefined."). [FN14] The procedure suggested by Defendant would simply ignore these substantial problems with the class definition, with the commonality, typicality and predominance requirements, and with the incidental effects of certifying a class action in the hopes that an appropriate class will eventually arise from the Court's findings. "[W]hile a court 'should not decline to certify a class because it fears that insurmountable problems may later appear,' if the court finds 'that there are serious problems now appearing, it should not certify the class merely on the assurance ... that some solution will be found.' " *Andrews v. American Telephone & Telegraph Co.*, 95 F.3d 1014, 1023 (11th Cir.1996) (quoting *Windham v. American Brands, Inc.*, 565 F.2d 59, 70 (4th Cir.1977)); *Castano*, 84 F.3d at 741 ("[A] court cannot rely on assurances of counsel that any problems with predominance and superiority can be overcome."). Because conditional certification would require just such a leap of faith by the Court in this case, the request that the Court conditionally certify the class is rejected.

Conclusion

For the reasons set out above, and particularly because this case requires many individualized determinations, the Court has determined that this case does not meet the requirements of Rule 23 for certification as a class action. It is therefore

ORDERED AND ADJUDGED that the Motion for Class Certification is DENIED.

FN1. Two of the original Plaintiffs, Amelia Fernandez and Robert Nava, voluntarily withdrew as named Plaintiffs on June 30, 2003, and July 24, 2003, respectively.

FN2. In fact, the district court in this case, noting that neither the Seventh Circuit nor the Illinois Supreme Court had addressed this question, held that the "medical monitoring issue involves a controlling question of law as to which there is a substantial ground for differences of opinion" and, as such, certified the question for interlocutory appeal. *See Carey v. Kerr-McGee*, No. 96-C-8583, 1999 WL 966484 (N.D.Ill. Sept.30, 1999). The Seventh Circuit, however, declined to review the question on an interlocutory basis, and the case subsequently settled. *See* Order from the 7th Circuit, *Carey v. Kerr McGee*, No. 96-CH-1325 (7th Cir. Jan. 18, 2000); Minute Order, *Carey* (N.D.Ill. Sept. 6, 2000) (No. 96-CH-1325).

FN3. The Court notes that, although not mentioned at oral argument, the Utah Supreme Court has allowed an independent cause of action for medical monitoring requiring proof of eight elements. *See Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993). Were the Court inclined to certify a class in other states, Utah would thus appear a more likely candidate than either Colorado or Illinois.

FN4. Defendant argues that the 32 milligram minimum daily dosage would be more or less arbitrary, because there is no medical evidence to suggest that levels above that dosage increase the risk of injury. *See* Defendant's Memorandum Addressing the Morgenstern Study. Although any such determination of the medical merits must wait for trial, Defendant's argument does demonstrate that the class definition is fluid and would likely be subject to change.

FN5. For example, Metab-O-Lite and MetaboLIFT are two other diet products which formerly contained ephedra. See *Home page*, *at* http:// www.slimstore.com (last visited Sept. 17, 2003). As Defendant noted during oral argument, this could lead to a problem where some class members may honestly believe and aver that they took Metabolife 356, unaware of the slight variation between it and the name of the product they actually used.

FN6. The first half of the test concerns the adequacy of class counsel. *See Griffin*, 755 F.2d at 1532-33. Although the Court has no reason to doubt that Plaintiffs' counsel would adequately represent the class, the Court need not reach this question due to its findings on the other requirements of Rule 23.

FN7. Defendant also suggests that these issues need not be reached, arguing that the medical evidence does not support that Metabolife 356 users can suffer any injury after they have discontinued use of the product, and that, therefore, none of these individuals, who have all stopped taking Metabolife 356, have standing to make a claim for medical monitoring. Defendant's Opposition at 9-10. Nonetheless, Plaintiffs have submitted an affidavit from a licensed medical doctor stating his opinion that the effects of Metabolife ingestion can result in chronic problems that will manifest themselves even after usage has stopped. Plaintiffs' Reply, Ex. 1 at 3-4. Therefore, any ruling that these Plaintiffs do not have standing would require a determination on the medical merits of the case that is impermissible at this stage.

FN8. Plaintiffs are correct that the Court may not deny certification based on a preliminary inquiry into the merits and a determination that the Plaintiffs are unlikely to succeed. *See, e.g.*, *Castano*, 84 F.3d at 744. However, the Plaintiffs' claim that "the Court must take the allegations of the Plaintiffs' Amended Complaint as true" is not entirely accurate insofar as it suggests

the Court may not look outside of the pleadings in making the class certification determination. *See* Plaintiff's Reply at 6. The Court, in fact, is permitted to "probe behind the pleadings before coming to rest on the certification question." *General Telephone Co. of Southwest v. Falcon*, 457 U.S. 147, 160, 102 S.Ct. 2364, 72 L.Ed.2d 740 (1982).

FN9. For example, Plaintiff William Burney testified that he had read the warning on the Metabolife 356 label, "evaluated them and didn't see a risk," and therefore did not consult a physician before trying the product. Defendant's Opposition, Ex. 6. Plaintiff Patricia Berni similarly admitted to having read the label, looked at the ingredients, and decided to buy the pills because she "didn't see anything that was dangerous for your health." Defendant's Opposition, Ex. 8. The absence of information in Defendant's opposition about some of the other Plaintiffs' deposition testimony regarding these labels suggests that some may not have paid such close attention to the warnings.

FN10. Although there is some suggestion in *Petito* that plaintiffs who prevail under a medical monitoring cause of action would not be foreclosed from claim splitting, thus allowing them to bring a suit if they later suffer an actual injury due to the exposure, this is certainly not a well-settled or well-tested legal principle.

FN11. The Court notes that one district court did find a medical monitoring claim warranted class certification under Rule 23(b)(1)(A) "because separate adjudications would impair [the Defendant's] ability to pursue a single uniform medical monitoring program." *In re Telectronics Pacing Systems, Inc.*, 172 F.R.D. 271, 284 (S.D.Ohio 1997). However, that case can be distinguished from the present case. First, the class complaint alleged only one "direct and immediate wound" that was the same for all plaintiffs--fracturing of the "J" leads of an implanted medical device that allegedly caused damage to each patient's heart--rather than involving "a latent, difficult to diagnose disease" in which "individual causation question[s] tend[ ] to be overarching." *Id.* at 289. This case, on the other hand, allegedly involves not only one, but several "latent, difficult to diagnose disease[s]." Thus, it is particularly unlikely that a uniform medical monitoring regime could be set up that would account for the individual differences that would be involved. Second, the *Telectronics* medical monitoring program required research into "better ways to detect the fractures." rather than relying on the established medical techniques recommended by Plaintiffs in this case. *Id.* at 285; Plaintiffs Motion, Ex. A at ¶ 14 (listing the established medical procedures to be included in the medical monitoring regimen). Third, that consolidated case already involved over 400 individual actions that were pending across the country, thus making conflicting orders much more likely. *Id.* Finally, that court itself noted that the class was being certified largely only because it appeared "to be the exception to the general rule that medical products liability actions require extensive proof of individualized issues." *Id.* at 288.

FN12. Although it will not go into effect until December, 2003, subject only to the unlikely possibility that Congress will reject the change entirely, the Supreme Court has approved an amendment to Rule 23(c) which would delete the reference allowing class actions to be "conditional." *See* Transmittal Letter from William Rehnquist, U.S. Supreme Court Chief Justice dated March 27, 2003, and Amendment to Rules of Civil Procedure, *available at* http://www.uscourts.gov/rules/congress0303/CV- Letters.pdf (last visited Sept. 16, 2003). While the Judicial Conference Report notes that courts will continue to have the ability to redefine or decertify a class action, that Report also indicates that the purpose of the deletion is "to avoid the unintended suggestion, which some courts have adopted, that class certification may be granted on a tentative basis, even if it is unclear whether the rule requirements are satisfied."

Committee on Rules of Practice and Procedure, *Report of the Judicial Conference* at 12 (Sept.2002), *available at* http://www.uscourts.gov/rules/jc09-2002/Report.pdf.

FN13. For example, the class might be very small if the medical evidence supports that only people who took six pills a day for more than three months are at increased risk of injury, whereas it would be much larger if taking only one pill ever were sufficient to increase the risk. The parties' litigation and settlement strategies could be quite different if they knew the approximate size of the class.

FN14. In reversing certification of a class in another case, the Eleventh Circuit stated that "[o]nce one understands that the issues involved in the instant case are predominantly case-specific in nature, it becomes clear that there is nothing to be gained by certifying this case as a class action; nothing, that is, except the blackmail value of a class certification that can aid the plaintiffs in coercing the defendant into a settlement." *Rutstein v. Avis Rent-A-Car Systems, Inc.*, 211 F.3d 1228, 1241 n. 21 (11th Cir.2000).

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